MEETING REPORT

Liability and other Legal Issues for Organizations Engaged in Product Development through Public-Private Collaboration

Initiative on
Public-Private
Partnerships
for Health

ALLEVIATING THE HEALTH CONSEQUENCES OF
POVERTY BY ENHANCING PUBLIC-PRIVATE COLLABORATION

Liability and other Legal Issues for Organizations Engaged in Product Development through Public-Private Collaboration

Report of a Meeting Organized by the Initiative on Public-Private Partnerships for Health

Convened at the Rockefeller Foundation
New York, NY, USA
14–15 April 2003

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Preface

This document summarizes discussions held on 14–15 April, 2003, at the Rockefeller Foundation in New York, concerning liability and other legal issues for organizations engaged in product development through public-private collaboration. The meeting report aims to enable partnerships to identify activities that may expose them to risk and other liability and to provide general guidelines for establishing a risk management program. It does not cover every potential situation, nor is it intended to provide categorical guidance. It is only a starting point for considering these issues. When analyzing its risk management program, organizations should always confer with legal counsel and risk management advisors.

The Initiative on Public-Private Partnerships for Health will be gathering additional material to post on its web site for the use of a Liability and Risk Management Counterparts Network, as part of our ongoing efforts to assist those engaged in product development through public-private collaborations. Further information can be obtained from info@ippph.org.

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Executive Summary

On April 14–15, 2003, a meeting organized by the Initiative on Public-Private Partnerships for Health and hosted by the Rockefeller Foundation, was held to discuss "Liability and Other Legal Issues for Organizations Engaged in Product Development through Public-Private Collaboration." Approximately 35 participants representing almost 30 organizations attended the meeting held at the office of the Rockefeller Foundation in New York City.

This meeting report is targeted toward those persons within a drug development public-private partnership ("PPP") who are responsible for assessing risk and/or providing risk management services and is designed to offer a summary of the principal liability and risk management issues which should be considered by the PPP's management, together with their legal, insurance and other advisers. The report pulls together the various presentations made by the legal and risk experts as well as the PPP practitioners at the meeting. It is not meant to be an exhaustive guide on the subject, but rather a starting point to become familiar with the issues at hand.

At the outset it should be noted that risk analysis and management should not be attempted by a small organization on its own. Outside legal, risk and insurance advisors should be consulted, as appropriate, throughout the risk management process. Risk management is an ongoing process; research ventures, diseased populations, and legal environments undergo constant change, requiring that risk be continuously managed.

Managing risk for a PPP involves the same basic process as for any other organization -- whether it is a commercial or nonprofit entity -- it includes identifying sources of risk, assessing the magnitude of risks and then determining the best options available to guard against them. The principal areas of risk as outlined in the 'Risk Rainbow,' discussed in the paper and inserted in the appendix, include property risk, personnel, operational, administrative and financial issues.

This report focuses on some of the operational issues relevant to product development PPPs. Specific to a public-private collaboration involved in drug development is the assumption of potential areas of liability or litigation in the research, development, and delivery of drugs and vaccines, particularly concerning clinical trials in developing countries and product liability issues. These issues can greatly complicate the risk management analysis when multiple jurisdictions and countries are involved, as is often the case with PPP's seeking new products for neglected diseases. Determining where and under what form the entity should be formed is a primary start-up issue, along with developing governing bodies' composition, and gaining early familiarity and compliance with tax and regulatory authorities.

The report identifies the major elements of risk to a PPP through product development and manufacturing. It covers regulatory and protocol considerations, potential litigation scenarios and the legal basics applicable to non-profit institutions. The paper summarizes various risk management techniques for conducting a risk assessment, the regulatory factors impacting on risk assessment, and other potential risk areas that should be managed. It describes what the responsible parties within a PPP need to think about to systematically identify the nature of risk and need to do to conduct R&D activities in a manner intended to best reduce such risk. A general discussion is included about how risk is assumed, who may assume such risk, and what can be indemnified. A section describes how to identify appropriate insurance resources, manage those resources so a PPP can be provided with optimal insurance coverage, and reduce potential

liability through management and administrative control.

The regulations of the U.S. Food and Drug Administration (FDA) relating to drug approval and the conduct of clinical trials need to be carefully followed, even if the intended destination is in developing countries. Informed consent and disclosure are primary concerns and are touched upon generally in the report. The paper lays out the basic issues surrounding contract and licensing concerns for a PPP. One section discusses product liability issues in the United States. Another section points out liability and risk management issues in Switzerland, Uganda, and South Africa. A list is provided of the key issues for which legal counsel and outside risk managers can provide assistance. The last section summarizes the next steps identified at the meeting.

Introduction

Within the last five or so years, there has been a marked increase in the number of groups attempting to develop tools to combat the diseases and other health problems associated with poverty, through so-called 'public-private partnerships' (PPPs) involving both public agencies such as the World Health Organization, government bilateral aid institutions, foundations funding public health such as the Bill & Melinda Gates Foundation and the Rockefeller Foundation, and private sector entities such as pharmaceutical and biomedical companies.

This phenomenon arises from an increasing recognition that, while the expertise to turn scientific research into useful health products (drugs, vaccines, diagnostics, contraceptives, microbicides, insecticide treated bednets, etc.) resides overwhelmingly in the private sector commercial industry, the commercial incentives do not currently exist to provide these tools to the poor populations that need them. Therefore collaboration between the public and private sectors is necessary to develop new, affordable medicines for infectious diseases that disproportionately affect people in the developing world.

The product development PPPs that have been established have had to basically write their own scripts since they have had only limited examples of successful cross-sector partnerships upon which to model their organizations. Most have needed to find unique ways to combine adapting business methods in the pharmaceutical sector for product development -- whether it is a portfolio or project management approach -- along with modifying public and nonprofit sector methods of fund raising, public relations, and political networking to accomplish their goals. This combination has created a new area for liability and risk management related to a fusion of traditional pharmaceutical, nonprofit charitable organization, and public sector issues.

Product development PPPs are often led by a chief executive officer who has background either in corporate pharmaceutical R&D or in the scientific public sector but seldom has experience running a small nonprofit organization. Consequently, PPPs have had steep learning curves in terms of start-up and administrative issues, especially if they are established as independent entities (e.g. Medicines for Malaria Venture, International AIDS Vaccine Initiative, Global Alliance for TB Drug Development). Even those product development PPPs that are embedded within a host organization (e.g. Malaria Vaccine Initiative at PATH, Pneumococcal Vaccine ADIP at Johns Hopkins University), have had to learn how to negotiate the structures and procedures that control risks associated with their operations.

IPPPH has endeavored to help PPPs navigate these unchartered territories and move up the learning curve by systematically documenting the PPP phenomenon, advising on organizational and operational issues, and increasing inter-partnership communication and networking. The fact that the product development PPPs are at various stages in their life cycle means that the emerging partnerships can benefit from the mistakes and successes of older ones and PPP management is usually quite willing to share information and learn from others. In order to enhance the effectiveness of these public-private collaborations, IPPPH periodically surveys the PPPs to find areas of mutual concern and conducts research or convenes meetings that focus on issues synthesizing knowledge to date in the field.

The current topic of liability and risk management had surfaced repeatedly in the various exchanges IPPPH had had with the PPPs involved in developing new tools of intervention in neglected diseases, particularly as these groups progressed further along the R&D pipeline towards clinical

trials and product introduction. To implement this meeting IPPPH teamed with The Rockefeller Foundation, which has been a key 'incubator' and funder of product development partnerships through its Health Equity theme in which it supports advocacy, capacity building and support for specific product development initiatives that can effectively harness the new sciences to counter market failures on essential health products.

1. Overview - Why Manage Risk?

All organizations, whether for profit or non-profit, must manage risk. Risk management includes continuous measurement, assessment, and analysis of potential risks and liabilities unique to an organization that would prevent it from accomplishing its mission. It also includes evaluation, planning, strategy formulation, transfer and auditing of such potential risks and liabilities. Risk management is essential for organizations engaged in product development through public-private collaboration. The general practice of risk management requires that a PPP analyze all the potential liabilities assumed in its operation, financial damage that may result from these liabilities, and ways to manage the potential risk of financial damages.

In addition, certain product development PPP activities will create potential risks and other legal liabilities unique to this type of venture. These include activities whose potential liability will affect a funders decision to contribute to the PPP, the potential of litigation for its activities, and the adverse publicity that will affect the PPP's ability to fulfill its mission. The activities, which may result in a PPP being involved in litigation in one or more jurisdictions, are research, drug and vaccine development, clinical trials, off-label use and the delivery of drugs and/or vaccines. This report summarizes each of these risks and provides a checklist for their identification and management.

2. Start-up Issues in Risk Management

Corporate law in each country determines what legal forms of existence and other forms of collaboration are available to the PPP, such as a not-for-profit corporation or foundation, and the jurisdiction(s) in which the PPP is to be formed. If the PPP is to operate in multiple jurisdictions, legal counsel familiar with the laws in each area should be consulted at the early stages of formation, to determine the relative risks of operating in each jurisdiction, the regulations relevant to those business activities and the applicable laws/regulations in those jurisdictions.

A PPP needs to carefully consider who should serve on its board of directors or advisory counsel, taking into consideration that its intended beneficiaries, funders, partners, host governments, and other stakeholders should be appropriately represented. These individuals will play a fiduciary role in the decision-making processes in the organization and therefore, their selection and participation is a critical step in the start-up phase.

In the United States, special attention should be paid at an early stage to Internal Revenue Service (IRS) regulations concerning not-for-profit corporations and Food & Drug Administration (FDA) regulations related to drugs and vaccines. In other countries, the requirements of the equivalent national tax authorities and regulatory approval agencies need to be well- understood in the early stages of PPP formation.

Besides these considerations particular to the start-up period, the remainder of issues covered in this report should be addressed at least in concept during the initial phases of creating a new PPP.

3. Potential Areas of Risk for Product Development PPPs

The potential extent of loss or the potential impact of failure are the primary elements of risk to a PPP's operations. The likelihood of this loss or failure depends on the nature of the injury, its financial, political or environmental impact, damage to the reputation of the PPP and disruption in the development or distribution of the product. Product development activities themselves also contain an element of risk. To determine the level of risk, the PPP must determine its level of activity in two aspects of product development – research and development (R&D). There is less risk in research than in development, but each involves risk and potential liability. During the research phases, although natural and synthetic chemistry can be toxic, most work is done as chemical research and experiments in a controlled laboratory setting. Development, however, involves pre-clinical safety studies and clinical trials involving animals and human subjects, thereby increasing the risk and cost. Regulatory and protocol considerations include U.S. FDA regulations (or those of the target countries), Institutional Review Boards (IRB) and Ethics Committees, particularly where trials involve human subjects.

Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.[1] The objectives of a research Ethics Committee are to maintain ethical standards of practice in research, to protect subjects of research and research workers from harm or exploitation, to preserve the human subject's rights, and to provide reassurance to the public that this is being done. Ethics Committees also protect research workers from unjustified criticism. World Health Organisation (WHO) and the Council for International Organisations of Medical Sciences have proposed international guidelines on biomedical research with regard to the role and functioning of a research ethics committee.[2]

Generally, product manufacturing of new drugs or vaccines involves greater risk as more persons may be injured. The potential liability issues are linked to the location and manufacturer of the product. If the manufacturer is not the PPP, should/can the risk of manufacture be transferred? If the manufacturer is a large pharmaceutical company, the PPP should explore the possible transfer of manufacturing liability in the appropriate jurisdictions. The pharmaceutical company is often the 'default' deep pockets for liability risk, so particular attention should be given to transferring manufacturing risk wherever possible. The large pharmaceutical companies are more likely to accept risk if there is a possibility that the development of the drug or vaccine has potential commercial value. If potential commercial value is negligible or nonexistent, the PPP may have to compromise on the liability issue if its partner resists accepting full liability.

Product risk will include, but not necessarily be limited to, adverse reactions to the product. The optimal time to try to shift liability risk is during the development stage, before manufacturing begins. This should be done by the parties involved at the development stage, which does not always include the manufacturer. If contract manufacturers are used for product development and/or manufacture, they generally will accept liability only for their own negligent acts. Large pharmaceutical companies are often more willing to accept liability during the development phase. However, in the clinical trial phase, they are likely to accept liability only if they conduct the trial and

[1] http://www.fda.gov/oc/ohrt/irbs/default.htm

[2] http://www.mrc.ac.za/ethics/committees.htm.

if the potential profits are high enough to either purchase insurance or self-insure. If the PPP is in partnership with a small biotech company, especially one in a developing country, shifting risk becomes less likely than with a large pharmaceutical company. A manufacturer is more likely to accept risk if the potential profit is high enough for it to either purchase insurance or – if it makes financial sense – to self-insure.

Since R&D occurs on a worldwide basis, the laws and potential liability in multiple jurisdictions must be assessed. However, a partner's agreement to accept liability in one jurisdiction may not adequately shift risk under the laws of another country, especially if the partner is a smaller-sized company. This means that the PPP must conduct adequate due diligence before engaging in manufacturing and, if possible, even before starting research, to determine whether the partner is willing to accept risk and, if so, whether that assumption is adequate in each appropriate jurisdiction.

Potential litigation scenarios

Litigation issues are complicated by fiduciary duty concepts because the PPP is in a position of trust. In commercial cases, aggressive risk management can sometimes be construed as an admission of liability. U.S. law is strict with fiduciaries who attempt cover-ups when something goes wrong, such as compensation to clinical trial participants who would never have consented to tests had they known the risks. In U.S. litigation, the plaintiff always points to a profit motive. This motive may not apply to a PPP and makes it an unprofitable defendant, since its mistakes are made with good intentions. For this reason, the PPP could be more pro-active in risk management to protect its potential to achieve good results.

Institutions and their volunteers, associated individuals, funders, officers and directors potentially all have liability concerns. Lack of knowledge on the part of directors and officers will in almost all cases not excuse them of responsibility, and PPPs should give careful consideration to providing directors and officers with liability insurance. This coverage is particularly important if its directors and officers are subject to litigation in the United States and may provide protection in other jurisdictions as well.

Common sources of liability are the programmed activities of institutions (for PPPs this would be research and development), governance and management activities of fiduciaries and the actions of volunteers or third parties attributed to an institution.

Legal basics applicable to non-profit institutions

Higher standards are often applied to non-profit institutions as advocates of the use of public funds for the public good. Directors have a fiduciary duty to the public they serve, including care, loyalty and obedience. The fundamental principle for professional money management, the so-called "prudent man rule," also applies to governance issues. The concept is that directors as fiduciaries may invest in a security or a project only if it is one that a prudent person of discretion and intelligence would invest in. Therefore, PPP advisory boards and/or scientific advisory committees need to understand that they may be held accountable for their investment decisions. Also the PPP must be fully cognizant of the relevant tax authority's rules on what constitutes a charitable organization. In the U.S., PPPs must comply with the new standards of accountability, recognizing that both the IRS and the state attorney generals have oversight responsibility for non-profit institutions in their jurisdictions.

4. Risk Identification and Likelihood Assessment

How to Identify and Manage Risk

Risk cannot be eliminated; it can only be managed or mitigated through either better control of the causes or reducing the consequences of outcomes. Ways of reducing the consequences includes transferring liability, in whole or in part, to a third party through contractual means or through insurance coverage. The ability to manage or reduce risk will vary with jurisdictional differences. The first step for a PPP is to identify its potential areas of risk and then to assess the possibility of such risk actually occurring. Risk management professionals can help in this area. See the 'Risk Rainbow' in Section 12 for factors which can be used in identifying risk.

Likelihood assessment

A PPP should start with its own internal assessment, appoint a person or persons to be responsible for risk management within the PPP and then engage competent legal counsel and/or an insurance or risk management professional for consultation at each stage.

The following elements should be considered in conducting a likelihood assessment:

- the structure of the organization
- the contractual arrangements with third parties
- the internal operating procedures
- the management process, controls, culture and environment.

A detailed review of each element, preferably with outside specialist input, is a critical component of the assessment process – which should include considering:

- the nature of each activity and its risks
- the extent of involvement by any donor, internal investigator, external collaborator and/or other sponsor
- the preparation of a judgment-based risk matrix
- the use of statistically-based techniques, with the assistance of outside risk management advisors to rank the risks for attention.

Regulatory factors in the United States

If a PPP can reasonably foresee that the U.S. may exercise jurisdiction when liability occurs, it should consider the regulations of the U.S. Food and Drug Administration (FDA) relating to drug approval and the conduct of clinical trials. There are three main areas that can affect public-private partnerships.

The first area concerns the Investigational New Drug Application (IND). A drug application cannot be approved without an IND being filed, and if the correct protocols are not followed, FDA approval may be withheld even if the IND is in place. The IND places strict guidelines on whether Good Clinical Practices (GCP) are being met. It imposes controls on the amount that can be charged for drugs in the trial, advertising guidelines for patients, and informed consent requirements. GCPs imposed by the FDA must be harmonized with the separate, but equally important, Good Manufacturing Practices (GMP) required by the U.S., Europe, and other jurisdictions throughout the world.

In accordance with GMP, pilot batches must be prepared with standardized potency, otherwise the FDA may rule that the drug or vaccine cannot be properly manufactured, and withhold its approval. The FDA should be contacted as early as possible in the development process. IND regulations also require that an Institutional Review Board (IRB) be put in place to set up procedures to monitor possible adverse drug reactions, etc. IRBs may be required by individual U.S. states and counsel should be consulted for specific state-by-state requirements.

Clinical trials

With respect to clinical trials, PPPs must be able to show that these are legitimate studies conducted to the highest scientific and ethical standards, since (if problems arise) regulators and lawyers may ask the following questions:

- How much money was paid to the institution or doctor(s) for the research? Were these 'normal' rates?
- Are there other relationships with such persons causing the PPP to pay more than is immediately evident for these services? (i.e. could other payments/grants be construed as 'kickbacks?')
- Was any data manipulated, not used, or discarded?
- Did the PPP take all possible steps to ensure the highest standards were followed?

In the U.S., disputes in these areas can lead to lawsuits by federal or state governments or to class action lawsuits by private parties.

Other legal factors to be considered regarding product use

Doctors in the U.S. have the right to prescribe approved drugs any way they want, even for conditions and diseases the drugs were never intended for, so-called "off-label uses." Legislation passed in 1997 allows drug companies to also promote off-label uses of their approved drugs (e.g. a drug approved for malaria treatment that seems to help in cancer patients, but is not yet approved for that use). However, the practice of off-label promotion subjects both companies and physicians – and any PPP associated with such a product – to a heightened chance of litigation stemming from an unapproved use of the drug. In general, this may be less of a concern for overseas PPPs that have no connection with the U.S. However, there is always a danger in advocating the use of a drug for an indication that has not been approved.

Health-care fraud and abuse is the number one source of insurance compensation in the U.S. and one of the fastest growing legal specialties. A PPP must be careful of adverse publicity to the organization and connections with any third party that may commit health care fraud and abuse with its products. Another area to avoid is being associated with any kickback scandal, which involves payments or other types of compensation made in order to influence and gain profit from an individual or company. In health-care fraud and abuse this form of bribery can include knowingly and illegally paying for the purchase of a drug outside normal drug purchasing channels. These abuses can lead to large fines or other punishment in the U.S. and possibly other jurisdictions. Likewise, a PPP should never prematurely or illegally promote a product. The advice of counsel should be sought to determine promotion laws in each jurisdiction.

5. Risk Management to Reduce or Eliminate Risk

As noted above, the PPP should systematically identify and assess risk on a consistent and continuous basis, covering all pertinent issues in its 'Risk Rainbow' (see attachment, Section 12). The principal items in the 'Risk Rainbow' include property risk, and personnel, operational, administrative, and financial issues. The risks that a PPP can most effectively control relate to its environment, health and safety regulations, business interruption and injury to reputation.

A systematic approach to risk management is essential. A PPP must identify territorial, procedural, and organizational scenarios. Not all risks are equal; therefore, the organization must assess each risk separately. The number of risks varies widely and depends on the position of the PPP in the product development process.

Risk transfer is not always the best approach to risk management as it is not always available and/or it may not be affordable. A PPP can transfer risk by either contractually shifting liability to a third party (e.g. getting a pharmaceutical company to assume responsibility for clinical trials or manufacturing), purchasing insurance coverage to reduce liability in case of occurrence, self-funding the risk, or in certain unique situations, creating a Limited Liability Company (LLC).

Other approaches to good risk management involve checking limits of insurance coverage and protocols – how they were established, whether they were followed. Identifying potential hazards, conducting an operability study and determining whether the PPP should increase or reduce its deductibles or coverage amounts provides a way to optimize insurance levels and thus mitigate certain risks.

The key factors that enable a PPP to minimize risk depends on the:

- extent to which the PPP is directly involved in the activities related to product R&D (less risk with passive vs. active involvement)
- level of day-to-day control/detailed supervision by the PPP
- frequency of written reports
- frequency of on-site visits
- level of oversight exercised by the PPP (PPP could be held responsible for ensuring best practices are followed)
- PPP providing funds or merely providing other resources or advocacy
- number of board members advising the PPP and their level of activity in the venture
- contractual limitations on liability
- possibility of creating a different entity to insulate the PPP from certain parts of the organization.

A PPP must constantly compare the cost of management control to the potential benefit of exercising such control.

Informed consent and disclosure

With clinical trials a failure to obtain a patient's informed consent before use of the product or participation in a clinical trial, or an approval or acquiescence in a wrong-doing no matter how far-removed could create serious liabilities for a PPP. The latter instance is more difficult to anticipate but the former is more easily preventable.

Care must be taken to obtain true informed consent, which consists of the patient or trial participant understanding the reasonable alternatives to the proposed intervention and knowing the relevant risks, benefits, and uncertainties related to each alternative. Liability may result if a clinical trial is non-consensual. Since informed consent for a minor is especially difficult, legal counsel should always be consulted when a clinical trial involves a minor, regardless of the jurisdiction. If trial participants are to be tested on informed consent understanding and

the patient has less than full understanding, then a protocol should be developed for the portion of consent which is not understood. One useful practice is to use local consultants to create a script for the investigators in the patient's native language through story telling.

Other potential liability concerns are the PPP's possible failure to disclose risk information or warnings to investigators and failure to report material information to health authorities. A PPP should be conservative in interpreting the intentions of patients and physicians. It should give as much information as possible to the health authorities, who are generally quite knowledgeable about clinical trials. A PPP must be careful that reimbursements do not become inappropriate inducements and/or compensation for participation as it can negatively affect informed consent. One approach is for a PPP representative to approach the clinical trial investigator, have a third-party physician visit the patient and then reimburse the patient for lost wages. This is effective for protecting and promoting the reputation of a PPP and meeting the requirements of regulators.

A transparent process is essential for obtaining informed consent. The PPP should try to prepare a script for every query and eventuality, especially in developing countries where multiple dialects or languages are spoken, translations may be imprecise and understanding more difficult. This is also good practice in industrialized countries as well. If there are special informed consent issues with respect to product liability and licensed and unlicensed experimental products, they often depend on the level of informed consent. Cases relating to injury in clinical trials are usually easier to defend because some risks are unknown and consent is usually broader. Only a few cases involving clinical trials have actually been brought before the courts in the U.S. and these have generally only occurred due to actions by the trial investigator or the drug company. There is also a strong incentive to settle clinical trial cases without publicity to avoid raising issues with the FDA. In the U.S., the statute of limitations for commencing a lawsuit is generally governed by state law. For example, in many states the limit is three years from the realization (not necessarily the occurrence) of an injury.

The contract/licensing concerns for a PPP

In managing risk involved with contracts and product licensing, a PPP may be able to shift responsibility to a third party or obtain indemnification from them. In the case of the latter, it is important to determine in advance that the financial condition of the indemnifying party is sufficient to make good on the indemnification. There are some differences among U.S. states on the ability of an entity to give indemnification and the scope of this indemnification. Except in the state of Vermont, indemnification is unavailable for intentional wrongdoing and for punitive damage. Another issue involves 'march-in' rights, which permit an entity to grant rights in an R&D project to a third party, usually the PPP, if the private industry collaborator does not commercialize the invention or if a public entity needs access to the technology to address a public health or safety concern. The PPP should be careful how 'march-in' rights are defined and exercised since it could end up assuming responsibility in the event the industry partner withdraws resulting in possible causation and liability.

In terms of trademark licenses, if a trademark is not policed rigorously, its improper use by others can create potential liability. Patent licenses are usually not a liability concern because the transfer of liability is straightforward. A material transfer agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations, for example, from industry to a research organization or PPP. MTAs are usually a question of fact, describing how the recipient intends to use it for his or her own research purposes and defining the rights of the provider and the recipient with respect to the materials and any derivatives. However, all these issues need to be managed properly to reduce risks to the PPP.

6. Assuming and Transferring Risk by Contract

Key contractual issues

Risk is often assumed by contract (as opposed to specific actions taken), and a key objective is to obtain contractual indemnification. The PPP should request inclusion as an additional insured to the assuming partner's insurance policy. However, even if the partner agrees to this condition, its insurer may not. Even if the insurer does agree, different definitions of "an additional insured" may be employed in the policy, and counsel should be sought to determine if the provisions of the policy offer adequate protection in the appropriate jurisdiction. Generally, this is less of an issue with larger pharmaceutical companies, but can be more of an issue in developing countries.

Individuals, institutions, donors and, in some rare cases, governments may assume risk.
However, academic institutions and governments usually cannot give indemnification. In general, governments have sovereign immunity and cannot be sued or held liable and therefore cannot provide indemnification to another party. It is also possible that other entities may have immunity in a particular jurisdiction. A thorough review of sovereign immunity should be made before entering into a formal arrangement with a third party to insure that it is authorized to provide indemnification. In dealing with such partners, the PPP must decide the amount of risk to shift to other third parties and/or the amount of risk to accept for itself.

Obtaining indemnification

Under best practice standards, indemnifications should be researched, negotiated, and signed before work begins. However, for practical reasons, the work will sometimes begin before the steps have been completed. In that case, the following issues should be considered: Who bears the risk? Who is responsible during 'hand-over' periods – the period when indemnification is being negotiated, but has not been finalized – and should the work be stopped until these issues are resolved?

Legal liability issues relating to drugs vs. vaccines.

There are differences in the nature and testing of drugs and vaccines. However, the potential risks of legal liability inherent in their research, development, and delivery may be similar. Greater risk may be acceptable for drugs that treat life-threatening diseases. Internal Review Boards and Ethics Committees are a frontline safeguard against liability and should be used consistently.

7. Management of a Casualty and Property Insurance Program

The first step in creating such a program is to determine the person in charge of internal risk management issues for the PPP. The risk manager can be the financial officer, the administrative officer, the in-house counsel (where such person exists), or other personnel. The second step is to find knowledgeable insurance resources such as insurance agents and brokers, defense attorneys, legal counsel and pharmaceutical industry experts. The Risk and Insurance Management Society (www.rims.org) is a good source for contacts in general and the Nonprofit Risk Management Center (www.nonprofitrisk.org) provides assistance and resources for nonprofit organizations. Brokers should be consulted for the best insurance information and advice. (Note: IPPPH has information on professionals who have proven useful for product development PPPs.)

Insurance coverage

A PPP should consider the following kinds of insurance coverage: catastrophe or umbrella liability insurance, professional liability insurance, staff coverage for those working on vulnerable projects. It needs to be noted that volunteers in an organization generally are not covered by policies in the U.S. A PPP should control its insurance information, understand all the details of the coverage, and communicate clearly to the insurer its mission, actions and entities within the organization. (see handout – Section 12). The PPP must promote itself to its insurers (as a good insurance risk), similar to how it would in a donor application, to get favorable treatment.

A PPP needs to manage its relationship with its insurance agent or broker (see handout –Section 12). With the assistance of outside advisors, senior management should determine the meaning of 'good service' and the amount of coverage needed. The broker should always be asked about the level of compensation - a reasonable standard is 10% to 15% of premium, and the type of service to be provided.

The dichotomy in claims management is whether to be aggressive and pay the claim or to follow the policy provision(s). The general rule is not to admit liability. However, this must always be discussed (and may ultimately be determined by) the insurance company, especially if a claim involves product liability.

A PPP must take a proactive approach to managing its casualty and insurance program. It should conduct a contract review for insurance, determine an appropriate level of coverage, and consider the possibility of being included as an additional insured under the policy of another party. Since there are many definitions of the term 'additional insured,' a PPP should always work with both its legal counsel and insurance broker, as insurers and lawyers will draft the definition of additional insured differently. In some cases, insurers may agree to cover new as well as existing projects, programs, activities, and entities and, in addition, extend coverage to donors.

A PPP should also develop disclosure and conflict of interest (COI) policies on a particular project and how actual, potential, or perceived COIs are disclosed by members of its Board, staff and consultants.

The following legal protections and legal defenses may be available to a PPP and should be discussed with legal counsel:

- the doctrine of *forum non-conveniens,* which is Latin for 'inconvenient forum.' Although there are rules that govern where a lawsuit must be filed, the location may be inconvenient for the witnesses or parties. If a party can prove that the location is inconvenient, the principle of *forum non-conveniens* allows a judge to decline to hear, or to transfer a case.
- the 'learned intermediary doctrine,' which assumes that the 'user' of the drug to whom the warning must be addressed is the prescribing physician who stands

between the product manufacturer and the consumer. If the physician has been adequately warned this is an absolute defense.

- informed consent (see above)
- no causation
- no valid scientific evidence for the claim
- off-label use (see above)
- the PPP has no duty to warn of unknown or unknowable risk
- charitable immunity
- liability limits
- volunteer protection laws
- indemnification agreements

Internal controls

A range of internal controls should be put in place within the PPP, governing administrative and operating practices. A few examples will illustrate: Conflict of interests -- if a Board member is involved in a particular decision, can it be shown that the purpose of the project was not just to make money for the board member?; IRS standards -- does the public benefit, for example, outweigh any private benefit going to an industry partner?; Non-profit status -- the IRS and other officials such as state Attorney Generals must be well-informed about any commercial purpose for a particular PPP product or activity. The PPP needs to have a systematic method for adequate documentation in all areas.

8. U.S. Product Liability: Risk Identification and Exposure Evaluation

Product liability – the U.S. perspective

From the U.S. perspective, not-for-profit product liability is generally governed by agreement. The PPP can potentially shift the risk by obtaining contractual indemnities from the pharmaceutical company or other manufacturer. The common plaintiff safety themes regarding product liability include: inadequate investigation; unresolved safety issues; a rush to market; and knowledge by the company, from the time of incident, that the device causing the injury was unsafe. A critical question is 'Do damaging documents and correspondence, including e-mails, exist that could have legal implications?' There are also intellectual property loss/theft, confidentiality, data protection, regulatory compliance and brand damage issues to consider.

The plaintiff's most common motive themes are that the company did not exert due care, pressured investigators into silence and hid the significance of problem from the FDA. The legal theories of the plaintiff are negligence, failure to follow a proper standard of care, breach of warranty, manufacturing or design defect and inadequate warnings. Regarding the failure to warn the patient, the plaintiff's counsel will try to prove that there was a known or scientifically knowable risk taken by the manufacturers, who are after all, the experts and must review all medical literature before it is disseminated. Other popular arguments include that there was a foreseeable misuse, for example, a change in dosage or regimen, that the manufacturer over-promoted the product to doctors and/or made a faulty assumption that an adequate warning was read and understood.

Under U.S. law, products of pharmaceutical companies are protected if accompanied by an adequate warning to the consumer. For prescription drugs, the 'consumer' is considered to be the treating physician, not the patient. However, legal counsel should be sought to determine compliance with consumer advertising laws.

9. Product Liability Issues in Switzerland, Uganda, South Africa

Switzerland

A. Essential features of Swiss Public Private Partnerships for Health ("PPPH")

Swiss PPPH are, in general, organized in the form of foundations governed by Article 80 et seq. of the Swiss Civil Code ("CC"). The mandatory "organs" of a Swiss foundation are the Board of the foundation, the Secretariat (executive organ) and the external auditors. There is great flexibility in the structure of a Swiss foundation. Additional organs or bodies such as for instance "scientific committees", "consultative committees" or "advisory committees" may be set up. Swiss foundations having activities outside Switzerland are supervised by the Swiss Supervisory Board for Foundations (the "Supervisory Board") which is part of the Swiss Department of Internal Affairs in Bern.

The members of the Board of a Swiss foundation may be Swiss or foreign nationals and may be domiciled in Switzerland or abroad. According to the most recent practice, as long as the Secretariat of a Swiss foundation is located in Switzerland, there is no requirement as to domicile or Swiss nationality of any Board member. In the event however that the seat of a Swiss foundation moves outside Switzerland, at least one Board member shall be domiciled in Switzerland.

The Board is the highest authority of a Swiss foundation. It is under the obligation to pay due attention to the execution of its duties. It is not under an obligation to succeed or to achieve results but to act with due diligence and care and in a manner aiming towards success.

According to Article 55 CC, corporate bodies act through their "organs". These "organs" bind the corporate bodies by their transactions and other acts or omissions. Thus, in principle, a foundation itself, rather than its organs or individual members of its organs, may be held liable towards its creditors, the founder or other third parties on contractual grounds or on the grounds of tort. There is in principle no liability towards the beneficiaries of a Swiss foundation.

Individual members of the Board of a Swiss foundation may be held personally liable in case of fault or any breach of their duty of care in the performance of their duties. For a director of a foundation to be held personally liable, the following conditions must be met: (i) a breach of the director's duties; (ii) a damage; (iii) a wilful or negligent conduct (fault); and (iv) a causal connection between the breach of duty and the damage suffered.

B. Privileges and/or immunities

Swiss not-for-profit foundations have in principle the possibility to obtain a tax exempt status at the federal and state level due to their not for profit aim. Such tax privileges are enjoyed by the foundation but in principle not by its employees, unlike the officers of an International Organisation ("IO") (i.e. an organisation the members of which are States) such as the World Health Organisation or the officers of a "quasi-intergovernmental organisation" (see next paragraph). It is noted however that some tax privileges in the form of additional tax deductions may be obtained by members of the top management of Swiss foundations.

Most PPPHs are non-governmental organisations ("NGOs"). They do not enjoy special privileges or immunities. In particular, unlike an IO, they do not enjoy any immunity of jurisdiction. It is noted that, rather exceptionally, Swiss practice recognises special status to legal entities which are in-between IOs and NGOs, the so-called "quasi inter-governmental organisations". In order to be qualified as a quasi inter-governmental organisation, a foundation shall fulfil various cumulative conditions, in particular: (i) have a non profit purpose; (ii) have as a majority of its members States or bodies subject to public law; and (iii) the majority of its financing shall be

through public funds. The special privileges or immunities (such as tax privileges and immunity of jurisdiction) that may be enjoyed by a quasi inter-governmental organisation and its officers should in principle be negotiated when the foundation is set up and formalised in a Seat Agreement between the quasi inter-governmental organisation and the Swiss Government.

C. Product liability for drugs, vaccines and other health products in Switzerland

The liability issues that may arise in an international context such as in relation to the production or distribution of drugs or vaccines in developing countries by Swiss based Public Private Partnerships for Health ("PPPHs") are not necessarily subject to the Swiss courts or to Swiss law. As a matter of principle, according to Article 129 I of the Swiss Private International Law Statute ("PIL"), lawsuits based on unlawful acts are subject to the jurisdiction of the Swiss courts at the domicile of the defendant. As far as the applicable law is concerned, according to Article 135 PIL, claims based on a defect or a defective description of a product such as a drug or vaccine are governed at the option of the damaged or injured party: (i) by the law of the country where the party responsible has his or her business establishment or habitual residence; or (ii) by the law of the country where the product was acquired, unless the party responsible for the damage can prove that the product was introduced on the market in that country (such as a developing country) without his or her consent.

Should Swiss law be applicable, a product liability claim will be governed by the Product Liability Statute of 1993 ("PLS"). The PLS imposes strict liability on the producer and does not take into account any element of fault. There are:

- no published cases of Swiss courts on product liability involving drugs, vaccines and other health products;
- no published cases of Swiss courts concerning the recognition and enforcement in Switzerland of foreign judgements based on product liability involving drugs, vaccines and other health products.

In general, there are very few cases in Switzerland concerning product liability. Various reasons may explain that, in particular the fact that, unlike in the USA, there are no class actions, no contingency fees and no treble damages in Switzerland. In addition, according to Article 135 II PIL, punitive damages pronounced abroad are in principle not recognisable and enforceable in Switzerland. Programs such as the Vaccine Compensation Injury Program are administered by individual Swiss cantons (i.e. the State and not the federal level). There has only been one case of compensation on record.

D. Liability for clinical trials in Switzerland

Concerning liability for clinical trials, the Federal Act on Medical Products and Medical Devices ("Law on Therapeutic Products") of 15 December 2000 prescribes that full and complete compensation for injuries suffered in the course of trials shall be guaranteed to the research subjects. Clinical trials may be undertaken only if provision has been made for the insurance and indemnity to cover the "investigator" and the "sponsor". The "investigator" is defined as any person responsible for the conduct of the clinical trial at a trial site. The "sponsor" is defined as any individual, company, institution or organisation which takes the responsibility for the initiation, management and/or financing of a clinical trial. The sponsor is responsible for any damage suffered by an individual who participates in a clinical trial. The sponsor shall cover this responsibility for him and the investigator by obtaining insurance cover for contractual and extra-contractual liability vis-à-vis the research subjects. If the sponsor is located abroad, he shall designate a person located in Switzerland who guarantees his liability.

Uganda

The Ugandan government is known for being receptive to public-private sector initiatives. Since the country suffers from a high prevalence of disease and offers a large pool of potential volunteers, it makes an opportune developing country location for clinical trials. From the legal point of view, another attraction is that the judicial regime is not as litigious as the U.S. and there is virtually no civil or criminal litigation arising out of clinical trials. Informed consent may be difficult to obtain as the general population has a low level of literacy and may not understand the risks from participating in a clinical trial. There may have been significant fraud and forgery of consent forms and doctors often exert undue influence over their patients. Generally, there is a

poor flow of information between regulators and parties conducting the clinical trials.

To the extent they exist, civil liability suits are generally based on:

- failure to comply with applicable law or government regulations
- violation of professional ethical guidelines
- breach of contract
- willful misconduct or negligence
- breach of fiduciary duties
- failure to adequately disclose risks
- violation of human rights
- vicarious liability of actions for agents, employees, etc.

Criminal liability is based on applicable penal law and other statutes, willful misconduct, gross negligence or vicarious liability. Criminal liability is often determined when the action involves the unauthorized sale of drugs, not defective products, and most cases are settled out of court.

South Africa

Even though South Africa's legal system is evolving, the courts are still somewhat conservative in applying standards of liability. Individuals may have personal liability for acts performed while participating in a clinical trial in South Africa. Therefore, malpractice insurance is recommended, if it is available. Persons or entities conducting clinical trials must establish the purpose of the product being tested and/or developed. When minors are being vaccinated, there must be compliance with ethical guidelines that require 'negligible risk' to minors. If minors younger than 16 years old participate in the clinical trial, additional insurance is required. This insurance can protect against civil liability, but does not cover criminal liability. There are three types of actions for liability arising out of a clinical trial, or the manufacture and distribution of a drug or vaccine: financial loss, pain and suffering, and an intentional, wrongful and negligent act. The general test is whether society approves of a particular action. The standard of wrongfulness is decided by a judge, as there are no jury trials in South Africa. Due to changes in the bench since 1994, the standard of wrongfulness is changing, but is still relatively conservative. The negligence standard, which is generally applied, is whether a diligent individual put in the position of a defendant could reasonably foresee that the defendant's conduct could cause injury and that steps could have been taken to avoid the injury.

The courts are now beginning to look at the plaintiff's actions to determine if the injury could have been avoided, if the plaintiff had been diligent. Defenses against wrongfulness include the issues of authority, self-defense, necessity, provocation, contributory negligence – for example, the plaintiff shared medication, and informed consent. The particular difficulty with informed consent in South Africa is that the country has eleven official languages, so there are potential issues arising both from translation and understanding. In South Africa, the injured person, the spouse or any dependents of the injured person may sue any person, a joint wrongdoer or anyone sharing vicarious liability.

For non-profit organizations in South Africa, the three applicable statutes are the Companies Act of 1973, the Trust Property Control Act of 1998 and the Non Profit Organizations (NPO) Act of 1997 which defines a non-profit organization. In terms of liability issues, personal assets cannot be attached. However, an NPO can sue and be sued since it is a legal entity. An NPO is subject to delictual actions such as tort claims and can suffer vicarious liability for the actions of its agents, employees and volunteers. Liability is best avoided through building careful relationship with all NPO partners, including the governments of developing countries. Community education is also a useful tool.

10. Expertise in Risk Assessment and Risk Management

Legal counsel can usually assist in the following areas affecting product development PPPs:

- issues relating to corporate law and the formation of the PPP
- potential liability of product development and manufacture
- potential liability of research and development in multiple jurisdictions
- product liability
- litigation, including the applicable statute of limitations
- compliance with rules and regulations in various jurisdictions, for example, in the U.S., FDA regulations and Sarbanes-Oxley oversight legislation
- potential liability arising out of the exercise of fiduciary responsibilities by the PPP. U.S. Internal Revenue Service rules on charitable organizations*
- standards of accountability
- contractual indemnification provisions
- the definition of additional insured in an insurance policy
- issues relating to health care fraud and abuse
- informed consent in multiple jurisdictions
- risk management and assessment, including review of insurance contracts
- development of conflict of interest policies
- protection from liability of PPP Board members

* Note: Fiduciary responsibilities extend to any person or persons affected during any phase of drug research, development, manufacture or use. Often it is viewed in broader terms, applying to all services provided to 'customers' by each person in an entity such as a PPP. The fiduciary responsibility of a PPP is taken by its top managers, who must ensure that all parties associated with the PPP keep a customer's well-being in mind at all times.

Risk managers are another resource available for assessing risk. There are two main types of risk managers: general risk management consultants and those who act primarily as insurance brokers/agents.

The key issues with which risk managers can assist include:

- risk assessment and identification
- comprehensive review of the 'Risk Rainbow' universe of risk management – see Section 12 for additional details.
- conducting a periodic survey to identify loss exposure
- evaluation of current insurance design
- insurance placement and marketing, including analysis of proposals from insurance carriers
- claims services
- insurance program administration
- local services in foreign countries
- evaluation of insurance company's financial condition
- preparation of an insurance manual as required
- actuarial analysis

See "Description of Insurance Broker Services" in Annex 1, p. 19-22 for detailed information.

11. Next Steps

The meeting participants proposed a variety of subsequent activities in various topic areas that are summarized below. Some of these will be undertaken by the Initiative on Public-Private Partnerships for Health, subject to the availability of financial resources.

1. *What constitutes Good Practices?*

Identify how PPPs can best defend themselves against risk and legal liabilities by meeting best standards of practice.

(*a*) Cost effectiveness of current efforts:
- What are PPP current practices?
- What does a PPP get for its money?

(*b*) Risk assessment guidance
- How to do it?
- How to go through the 'risk rainbow' internally?

(*c*) Monitoring of clinical trials in developing countries.
PPPs shouldn't just pay subcontractors for trial oversight; they need to be directly involved in seeing standards are met. e.g. they need to know what the FDA requirements are for informed consent. Identify current practices.

2. *Insurance*

(*a*) Develop a list of insurance providers in this area.
(*b*) Study "pool" ideas, self-insuring, and captive insurance vehicle.
(*c*) Conduct 'cost-of-insurance' survey
(i) Who should be involved to educate the PPP?
(ii) What is a "good risk" profile?
(*d*) Market updates – tracking of insurance costs in different markets.

3. *Global Claims*

(*a*) Claims and adverse events:
(i) Is there a database of industry experience or frequency of claims on clinical trials?
(ii) How frequently do claims and adverse events occur in developing country clinical trials?
(*b*) Discuss with agents and brokers in Global Insurance List.
(*c*) Develop country specific information
(i) Where are clinical trials currently being conducted in addition to known sites in Gambia, Nigeria, South Africa, Thailand and Uganda?
(*d*) Develop information on out of court settlements (claims and adverse events – can we get anecdotal lists including numbers and amounts?)
(*e*) Contact risk managers of large pharmaceuticals, if possible, for additional guidance.

4. *Lobbying*

Government solutions could be developed for: U.S., Europe, other participating countries.

5. *Intellectual Property*

(*a*) Tie into existing work of the Rockefeller Foundation and Center for Management of Intellectual Property in Health Research (MIHR).
(*b*) IPPPH paper forthcoming with WIPO IP expert.

6. *Resources and Priorities*

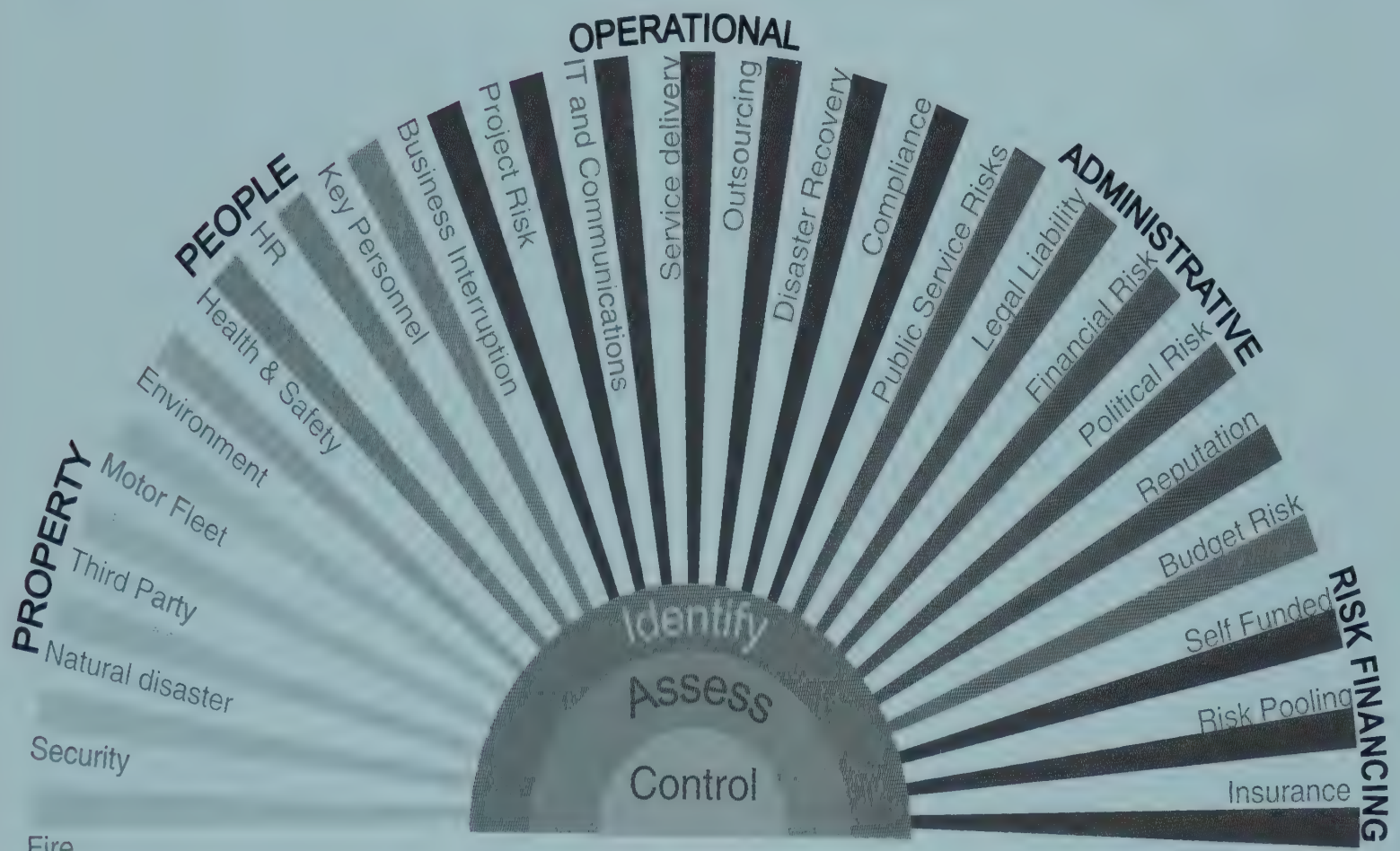
Determine how to prioritize these ideas and identify how will work be paid for?

Annex 1: Presentations

This section includes three presentations made at the meeting for easy referral:

- Risk Rainbow from Willis Ltd. (p. 2 of Winter/Hazell PowerPoint)
- Description of Broker Services from Risk Resources, Inc. (Randy C. DeLopst)
- List of Presentations and Presenters from Meeting

The remainder of the presentations are accessible on-line to members of the IPPPH Counterparts Network on Liability and Risk Management at www.ippph.org or available to others upon request from info@ippph.org.



The Risk Rainbow

Source: Tracy Hazell, Willis Ltd

Description of Insurance Broker Services

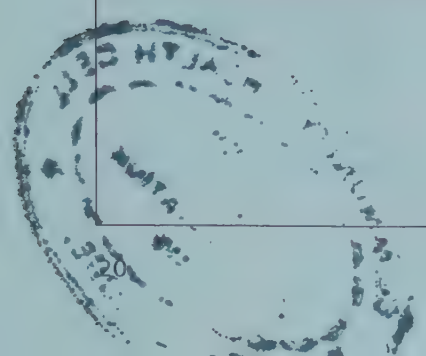
Randy C. Delopst, Risk Resources, Inc., Elmhurst, IL

Service Description	Service Need		
Risk Management Services	Annual	When Requested	Not Needed
1. Periodic survey of client's business operations to identify loss exposures.			
2. Site visits to major locations.			
3. Evaluate current insurance program design. Identify and evaluate alternatives. Recommend improvements. (structure, limits, scope of coverage, retentions, etc.)			
4. Review contracts for risk management/insurance implications.			
5. Provide assistance with Disaster Recovery Planning.			
Insurance Placement/Marketing	Annual	When Requested	Not Needed
1. Evaluate the competitiveness of current insurance premium pricing and rate levels.			
2. Obtain competitive proposals for coverage lines where necessary.			
a. Prepare insurance coverage specifications.			
b. Compile underwriting rating and claims data.			
c. Complete underwriting applications. Service Description.			
d. Analyze proposals when received and make recommendations.			
e. Review issued insurance policies for compliance with accepted proposal terms.			
3. Conduct renewal process with existing insurance carriers.			
a. Compile renewal rating and loss information.			
b. Complete renewal applications.			
c. Review coverage terms and attempt to obtain broader terms.			

Description of Insurance Broker Services

Randy C. Delopst, Risk Resources, Inc., Elmhurst, IL

Service Description	Service Need		
Insurance Placement/Marketing (Cont'd.)	Annual	When Requested	Not Needed
d. Analyze renewal proposals and make recommendations.			
e. Review issued policy for compliance with renewal proposals.			
Claims Services	Annual	When Requested	Not Needed
1. Process claim notifications to appropriate insurance carriers.			
2. Monitor and follow-up on large claims to speed the settlement process.			
3. Review claim reserves and evaluate the accuracy of reserve levels.			
4. Perform claim audits to evaluate the claim handling performance of the insurance carrier or TPA. Assume review of _____ files per year.			
5. Attend claim review meetings. Assume attendance at _____ meetings per year.			
6. Review loss runs on a periodic basis. Review loss runs for accuracy and correct mistakes.			
7. Review, analyze and negotiate claims service standards and agreements with insurance carriers or TPAs.			
8. Monitor, review and assess cost containment efforts.			
9. Help client adjust the loss with the insurance co. (Property & Crime losses)			
10. Review denied claims for correct coverage application.			



Description of Insurance Broker Services

Randy C. Delopst, Risk Resources, Inc., Elmhurst, IL

Service Description	Service Need		
Insurance Program Administration	Annual	When Requested	Not Needed
1. Process policy changes, additions/deletions, premium invoices.			
5. Issue auto ID cards. Assume _____ number of vehicles annually.			
6. Review annual premium audits. Verify accuracy and correct mistakes.			
7. Verify the accuracy of experience modification calculations.			
8. Review and negotiate letters of credit. Verify letter of credit levels are accurate.			
9. Process ERM 14 filings where needed.			
10. Review and evaluate retro adjustments.			
11. Prepare and conduct client account review meetings. Assume _____ per year.			
12. Analyze paid loss billings, allocations and adjustments. Check accuracy and correct mistakes.			
13. Prepare periodic client reports describing open items, status of special projects and other relevant issues.			
14. Monitor property insurance reporting forms on a monthly/quarterly basis.			
15. Prepare and present annual stewardship report.			
16. Provide client with updates regarding market conditions.			
17. Answer client questions and provide research or advice as needed.			

Description of Insurance Broker Services

Randy C. Delopst, Risk Resources, Inc., Elmhurst, IL

Service Description	Service Need		
International Insurance Program	Annual	When Requested	Not Needed
1. Provide local services in foreign countries.			
2. Placement of local insurance coverages.			
3. Develop international insurance manual for client.			
Loss Control Services	Annual	When Requested	Not Needed
1. Perform loss control inspections at major locations.			
2. Review loss control inspection reports by insurers and comment.			
3. Review loss experience. Analyze and comment on loss trends, major causes of loss, etc.			
4. Provide safety training materials & seminars.			
5. Develop benchmark or peer group performance criteria for the client's loss experience.			
Special Services	Annual	When Requested	Not Needed
1. Due diligence for mergers or acquisitions.			
2. Risk management information systems design/ evaluation/implementation.			
3. Actuarial analysis - loss forecasting, retention levels, funding levels, loss development factors, etc.			
4. Captive insurance company feasibility studies.			
5. Preparation of insurance manual for client's divisions or subsidiaries.			
6. Evaluation of insurer financial condition.			
7. Provide client with educational services/seminars.			

List of Presentations

(in approximate order of presentation)

Robin Krause, Esq. Patterson, Belknap, Webb & Tyler, New York, NY
"Non-Profit Institutions and Liability in the U.S. Setting" (Powerpoint Slides)

Chris Hentschel, Chief Executive Officer, Medicines For Malaria Venture, Geneva, Switzerland
"Drug Development (and Beyond): Areas that could give rise to risk of liability" (Powerpoint Slides)

Regina Rabinovich, Director, Infectious Diseases, Global Health Program, Bill Melinda Gates Foundation, Seattle, WA
"Managing Risk: Comparisons Vaccines and Drugs" (Powerpoint Slides)

Tim Tucker, Director, South African Aids Vaccine Initiative, Cape Town, South Africa
"SAAVI's Operating Model, Liability, and Risks" (Powerpoint Slides)

Scott Bass, Attorney, Sidley Austin Brown & Wood Llp, Washington, D.C.
"U.S. Food and Drug Administration Regulatory Factors to Consider by Product Development PPPs" (No copy available)

Kenneth J. King, Partner, Patterson, Belknap, Webb & Tyler LLP, New York, NY
"Product Liability – The U.S. Perspective" (Powerpoint Slides)

Benoît Merkt, Attorney-At-Law, Lenz & Staehelin, Geneva, Switzerland
"Risk Identification and Exposure Evaluation in Sale and Distribution of Drugs, Vaccines and Other Health Products" (Powerpoint Slides)
"Non-Profit Institutions and Liability: The Example of a Swiss Non-Profit Foundation" (Powerpoint Slides)

Johnson Kwesigabo, Advocate, Kwesigabo, Bamwine & Walubiri Advocates, Kampala, Uganda
"Risks and Exposure in Development and Clinical Trials of Drugs, Vaccines and Other Health Products: The Ugandan Experience" (Word document)
"Risks and Exposure in Development and Clinical Trials of Drugs, Vaccines and Other Health Products: The Ugandan Experience" (Powerpoint Slides)
"Liability for Clinical Trials and Defective Products from the Perspective of Developing Countries: The Case of Uganda" (Powerpoint Slides)

Patricia Lambert, Legal Adviser to The Minister, Ministry of Health, Pretoria, South Africa
"Non-Profit Organisations & Liability: South Africa" (Powerpoint Slides)
"Aspects of the South African Law of Delict: Legal Liability for the Sale and Distribution of Drugs, Vaccines and Other Health Products" (Powerpoint Slides)

Tracy Hazell, Director, Global PPP Practice, Willis Ltd. London, UK and **John Winter**, Partner, Patterson, Belknap, Webb & Tyler LLP, New York, NY
"How to Reduce or Eliminate Risks: The Mysteries of Risk Management Revealed" (Powerpoint Slides)

Randy C. Delopst, Risk Resources, Inc., Elmhurst, IL
"How to Manage a Property & Casualty Insurance Program" (Powerpoint Slides)
"Description of Insurance Broker Services: A Checklist" (Word document)
"Property & Liability Insurance: Key Information Needed to Obtain Competitive Proposals" (Word document)
"Property & Liability Insurance: Buyers Guide" (Word document)

Eric Walker, Vice President for Administration, Finance and Human Resources, Program for Appropriate Technology in Health (PATH), Seattle, WA
"PATH's Journey into a Higher Risk Environment: A Quick Case Study" (Powerpoint Slides)

Simon Lazarus, Senior Counsel, Sidley Austin Brown & Wood Llp, Washington, D.C.
"United States Legislation as a Means of Limiting Liability for Drug and Vaccine Development for Third World Pandemics" (Word document)

Annex 2: Agenda

Monday, 14 April, 2003

9:00 a.m. – 9:30 a.m.	Welcome and Introductions *Roy Widdus, Initiative on Public-Private Partnerships for Health, Geneva, Switzerland* *Ariel Pablos-Mendez, The Rockefeller Foundation, New York, USA*
9:30 a.m. – 10:00 a.m.	Overview of program and setting the stage for discussions on risk management *Richard Wilder, Sidley, Austin, Brown & Wood LLP, Washington, D.C., USA* *Robin Krause, Patterson, Belknap, Webb and Tyler LLP, New York, USA*

10:00 a.m. – 10:15 a.m. – Coffee Break

10.30 a.m. – 11.30 a.m.	Overview of the processes of development of drugs, vaccines and other health products from risk management perspective *Drug Development – Chris Hentschel, Medicines for Malaria Venture, Geneva, Switzerland* *Vaccine Development – Regina Rabinovich, Bill and Melinda Gates Foundation, Seattle, USA*

[Note: This section is intended to be a general overview of the process of research, development and bringing a product (drug and vaccine) through regulatory approval and noting the areas in that process that could give rise to risk of liability. The later sections will expand on some of those areas – notably clinical trials and products liability when a product is brought into the market. Discussions later will cover similarities and differences for other products, e.g., diagnostics, and fortified foods.]

11.30 a.m. – 12.30 p.m.	Risk identification and exposure evaluation in development and clinical trials of drugs, vaccines and other health products *Scott Bass, Sidley, Austin, Brown & Wood LLP, Washington, D.C., USA* *Johnson Kwesigabo, Kwesigabo, Bamwine & Walubiri Advocates, Kampala, Uganda* *Tim Tucker and Mark Leibowitz, Medical Research Council, Cape Town, South Africa*

[Note: This section will focus on identifying the points in the product development process where risks arise. Products liability due to defective design and/or manufacture will be dealt with later. The principal focus in this section is to be on clinical trials – including informed consent and liability claims from adverse reactions in trials. The purpose will be to identify risks, elimination or mitigation of the risks will be dealt with in a following section. The focus will be in such liability from the perspective of trials in the United States, Europe, and some developing country jurisdictions.]

12:30 p.m. – 2:00 p.m. – Lunch

2.00 p.m. – 3.00 p.m.

Risk identification and exposure evaluation in development and clinical trials of drugs, vaccines and other health products
(Continued)

3.00 p.m. – 3.30 p.m. – Coffee Break

3.30 p.m. – 5.30 p.m.

Risk identification and exposure evaluation in sale and distribution of drugs, vaccines and other health products

Kenneth King, Patterson, Belknap, Webb and Tyler, LLP, New York, USA
Benoît Merkt, Lenz & Staehelin. Geneva, Switzerland
Johnson Kwesigabo, Johnson Kwesigabo, Kwesigabo, Bamwine & Walubiri Advocates, Kampala, Uganda
Patricia Lambert, Legal Adviser to the Minister of Health, Pretoria, South Africa

[Note: This section will focus on products liability actions. Again, the focus will be on products liability actions in the United States, Europe and some developing country jurisdictions.]

6.30 p.m. – 7.00 p.m. – Reception/Dinner
Cinque Terra Restaurant, 22 East 38th Street, New York
(Tel: 212 867 2260)

End of day one

Tuesday, 15 April, 2003

9.00 a.m. – 10.00 a.m.	How to reduce or eliminate risks: Methods and limitations of transferring risks to others *John Winter, Patterson, Belknap, Webb and Tyler, LLP* *Tracy Hazell, Willis Limited, London, UK*
10.00 a.m. – 11.00 a.m.	How to manage a casualty and property insurance program *Randy DeLopst, Risk Resources* *Chris Elias and Eric Walker, PATH, Seattle, USA*

11.00 a.m. – 11.30 a.m. – Coffee Break

11.30 a.m. – 12.30 p.m.	Panel discussion on risk identification, management and mitigation

[Note: This section will bring together a panel of the presenters from the first part of the seminar. The purpose will be to enable the participants to "put it all together" and ensure that any gaps from risk identification, to management, to mitigation do not remain.]

12.30 p.m. – 1.30 p.m. Lunch

1.30 p.m. – 3.00 p.m.	Non-profit institutions and liability *Dominique Hempel, The Global Fund to Fight AIDS, Tuberculosis and Malaria, Geneva, Switzerland* *Robin Krause, Patterson, Belknap, Webb and Tyler LLP, USA* *Patricia Lambert, Legal Adviser to the Minister of Health, South Africa*

[Note: This section is intended to focus on the range of legal obligations and risks for officers, board members, staff, host organizations, collaborators, funders, etc. of public-private partnerships. This section will look at the relevant law in the United States, Switzerland, and at least one developing country.]

3.00 p.m. – 3.30 p.m. – Coffee Break

3.30 p.m. – 4.30 p.m.	Are legislative initiatives possible to eliminate or mitigate risks to public-private partnerships? *Simon Lazarus, Sidley, Austin, Brown & Wood, LLP, Washington, D.C., USA*

[Note: The purpose of this section is to provide an overview of legislation in the United States and Europe where potential liability in drug and vaccine development and marketing have been mitigated, eliminated, or capped. The suggestion is that similar legislation may be considered for the activities of public-private partnerships.]

4.30 p.m. – 5.00 p.m.	Conclusions

5.30 p.m. Closure of meeting

Annex 3: List of Participants

Scott Bass
Partner
Sidley Austin Brown & Wood LLP
USA

Randy C. DeLopst
Risk Resources, Inc.
USA

Christopher J. Elias
President
Program for Appropriate Technology in Health (PATH)
USA

Charlotte Ellertson
President
Ibis Reproductive Health
USA

Henry Gabelnick
Director
CONRAD
USA

Charles A. Gardner
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The aim of the Initiative on Public-Private Partnerships for Health is to increase the effectiveness of public-private collaboration, particularly by helping those seeking to develop health products, or to improve access to such products needed to fight neglected diseases and other health problems in developing countries.

Created in 2000 in Geneva, Switzerland, the Initiative on Public-Private Partnerships for Health is sponsored by the Bill and Melinda Gates Foundation, the Rockefeller Foundation and the World Bank. It operates under the aegis of the Global Forum for Health Research, an independent international foundation helping to correct the 10/90 gap in health research, from which it also receives support (www.globalforumhealth.org).

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